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EXAMINER
PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
1651	7

DATE MAILED: 09/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/067,991

Applicant(s)

FISCHETTI ET AL.

Examiner

Francisco C Prats

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-47 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 8-47 is/are rejected.
- 7) ☒ Claim(s) 47 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1651

DETAILED ACTION

The preliminary amendment filed February 8, 2002, has been received and entered. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). In the instant case claim numbering was re-started at claim 21 after claim 24. See page 12 of the preliminary amendment filed February 8, 2002.

Misnumbered claims 21-43 have been renumbered 25-47. Claims 8-47 are pending and are examined on the merits.

Claim Objections

Claim 47 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 30. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Applicant is advised that should claim 30 be found allowable, claim 47 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "lysin enzyme characterized by the ability to specifically destroy the cell wall of Group A Streptococci" in claims 8 and 37 renders those claims and their dependents indefinite. It is not clear how the term "specifically" qualifies the cell wall destruction performed by the enzyme, or

Art Unit: 1651

what degree of specificity is required, or how that degree of specificity is to be measured and compared to the degradative specificities of other enzymes. Note that during prosecution this term will be construed to encompass any lysin enzyme capable of destroying the cell wall of Group A Streptococci, since that property is by definition specific.

Claim 28 is indefinite because the term "said mammal" lacks antecedent basis in the claims. The term "mammal" does not appear anywhere in the claims before the recitation "said mammal" in claim 28. Claim 45 is indefinite for the same reason.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the

Art Unit: 1651

United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 8-12, 18, 24-35 and 41-47 are rejected under 35

U.S.C. 102(b) as being anticipated by Ogawa et al (U.S Pat. 3,786,141) in light of Sokawa et al (J. Biochem. 57(1):64-74 (1965)).

Independent claims 8 and 37 require only two ingredients, (1) a phage-encoded lysin enzyme capable of destroying the cell walls of Group A streptococci, and (2) a carrier, which may be "liquid", for example, water.

Ogawa discloses the preparation of "a lytic enzyme prepared from the lysate of Bacteriophage ATCC No. 21597-b-infected Group C Streptococcus sp. ATCC NO 21597, according to the method described in the Journal of Biochemistry, vol. 57, p. 67 (1965)." See column 4, lines 7-11. Thus, Ogawa discloses the preparation of an enzyme from the identical phage strain used by applicant, using the identical host bacterial strain as applicant. See applicant's specification at page 26, lines 1-10; compare applicant's strains to Ogawa's.

Ogawa uses the disclosed enzyme preparation to lyse microorganisms (see Example 1 of Ogawa), so it is not clear from Ogawa whether the lysin preparation, prior to its use, is in an aqueous carrier solution suitable for administration according

Art Unit: 1651

to applicant's claims. However, Sokawa, the article clearly referred to by Ogawa, clearly discloses on page 65 that the precipitated enzyme preparation is "dissolved in M/75 phosphate buffer, pH 7.0, and lyophilized after dialysis against the same buffer in the cold." Sokawa, page 65, left column, second full paragraph. Thus, because Ogawa discloses that the enzyme preparation was made according to the disclosure of Sokawa, it is clear that Ogawa's enzyme preparation, prior to its use, was in an aqueous buffer solution, as required by applicant's claims. Moreover, in view of the fact that Ogawa used the same strains of phage and bacterium as used by applicant, there is no doubt that the prior art enzyme has the same activity as recited in the claims. Lastly, note that the presence of the enzyme in aqueous buffered medium reads on the claimed buffered and lyophilized compositions, as well as those applications (aerosol, nasal spray, etc.) to which aqueous and/or lyophilized compositions can be put. A holding of anticipation over the cited claims is clearly required.

Claims 8-12, 14, 15, 25-34 and 42-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Raina (J. Bacteriol. 145(1):661-663 (1981)).

Art Unit: 1651

Raina describes the purification of a lysin enzyme from Streptococcus Group C bacteriophage, a bacteriophage encompassed by the claimed strain. See abstract. The bacteriophage, in various stages of purification, is described as being present in several different aqueous buffer solutions comprising various buffers and/or agents encompassed by the claims including phosphate, EDTA and mercaptoethanol. See, e.g., sentence spanning left and right columns on page 661. Because Raina describes a composition comprising the claimed ingredients, and because the described compositions can be applied to those claimed uses (aerosol, nasal spray, etc.) suitable for aqueous compositions, a holding of anticipation over the cited claims is required.

Claims 8-18, 24-35 and 41-47 are rejected under 35 U.S.C. 102(a) or 102(e) as being anticipated by Fischetti et al (U.S. Pat. 5,604,109).

Fischetti describes compositions comprising the claimed enzyme, produced by culturing the same phage strain on the same bacterial strain as disclosed in the instant specification at page 26. See column 4, lines 15-65 (Example 1). The enzyme preparation is disclosed as being in the same buffer systems, in lyophilized form, as recited in the claims. Because Fischetti

Art Unit: 1651

describes a composition comprising the claimed ingredients, and because the described compositions can be applied to those claimed uses (aerosol, nasal spray, etc.) suitable for aqueous compositions, a holding of anticipation over the cited claims is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8, 9, 19, 31, 32 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raina (J. Bacteriol.

Art Unit: 1651

145(1):661-663 (1981)) or Fischetti et al (U.S. Pat. 5,604,109) in view of Roser (U.S. Pat. 4,891,319).

As discussed above, each of Raina and Fischetti discloses compositions comprising the claimed enzyme in an aqueous carrier system which can be administered according to the claimed intended uses. Neither Raina nor Fischetti discloses combining the enzyme compositions with a sweetener, as recited in claims 19 and 36. However, Roser clearly discloses that the sweetener trehalose is highly advantageous for use as an enzyme preservative. Thus, the artisan of ordinary skill, recognizing Roser's disclosure of the advantages of using trehalose for enzyme stabilization, clearly would have been motivated to have combined the enzyme disclosed by Raina and Fischetti with trehalose to have formed a stabilized enzyme composition. A holding of obviousness is clearly required.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

Art Unit: 1651

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 8-30 and 47 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-26 of prior U.S. Patent No. 5,997,862. This is a double patenting rejection. Note specifically that although the language describing the enzyme in the '862 patent differs from the language used in the claims of the instant application, the enzymes are in fact the same, having identical metes and bounds, based on the fact that the identical bacteriophage will produce the identical enzyme on the identical host bacterial strain. A statutory double patenting rejection is clearly required.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Art Unit: 1651

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 31-47 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 5,997,862. Although the conflicting claims are not of identical scope, they are not patentably distinct from each other because the patented claims recite subject matter which is entirely encompassed by instant claims 31-47. Moreover, a pharmaceutical composition comprising a lysin enzyme produced by phage C1 clearly suggests the "lysin enzyme genetically coded for by a bacteriophage" generically claimed in claim 31 herein. Thus, although the claims under examination contain subject matter broader than the patented subject matter, the claims under examination encompass subject matter clearly suggested by the subject matter previously patented by applicant. A terminal disclaimer is therefore clearly required.

Claims 8-47 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,017,528, claims 22-49 of U.S. Patent No. 6,056,955, claims 1 and 2 of U.S. Patent 6,277,399, and claims 1-10 of U.S. Patent.

Art Unit: 1651

6,423,299. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed use of a mammal in the '528 patent renders obvious the generic use claimed herein, which encompasses treatment of a mammal. Moreover, it is noted that certain of the patented claims recite the carriers in terms of intended uses which are different than the intended uses recited in the claims under examination herein. However, because certain carriers, in particular aqueous liquid solutions, can be used in a variety of different administration modes, the patented claims recite overlapping subject matter clearly suggesting the subject matter recited in the claims under examination. Because the patented claims suggest the subject matter claimed in the instant application, a terminal disclaimer is clearly required.


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

Art Unit: 1651

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Francisco C Prats
Primary Examiner
Art Unit 1651

FCP


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